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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/837,459	04/18/1997	MARIAN L. MCKEE	4995.0023	7600

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EXAMINER
PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
1645	35

DATE MAILED: 10/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/837,459	Applicant(s) McKee et al
	Examiner Portner	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sh et with the c rresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 2, 2002*.

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *60 and 66-96* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *60 and 66-96* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 72 has been canceled..

New Claims 91-96 have been submitted.

Claims 60, 66-70, 73-82 and 84-85 were amended.

Claims 60, 66-96 are pending and under consideration.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections Withdrawn

2. Claims 72-73, 75, 78, 82 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, in light of the cancellation of claim 72.

3. Claim 79 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, in light of the amendment of claim 79.

4. Claim 66 rejected under 35 U.S.C. 112, second paragraph for reciting the term"wildlife", in light of the arguments set forth in paper number 34.

5. Claim 68 rejected under 35 U.S.C. 112, second paragraph for reciting the host animal to be a "nursing animal" in light of the amendment to clarify the nursing animals to be producing milk.

6. Claim 69 rejected under 35 U.S.C. 112, second paragraph for defining the patient as "an offspring" of "a nursing animal", in light of the amendment to clarify the nursing animals to be producing milk.

Claim 70 rejected under 35 U.S.C. 112, second paragraph for reciting the patient is an animal and a newborn, in light of the amendment of the claim to delete the phrase "an animal".

Claim 72 rejected under 35 U.S.C. 112, second paragraph for reciting the methods step of butchering the animal, in light of the cancellation of the claim.

Claim 73 rejected under 35 U.S.C. 112, second paragraph for reciting the methods step of butchering the animal, in light of the amendment of the claim to no longer recite the methods step of butchering the animal.

Claim 74 rejected under 35 U.S.C. 112, second paragraph, in light of the amendment of the claim to clarify the methods steps being carried out.

Claim 75 rejected under 35 U.S.C. 112, second paragraph, in light of the amendment of the claim to delete the term "butchering" and clarification of the methods step being carried out.

Claim 78 rejected under 35 U.S.C. 112, second paragraph, in light of the amendment of the claim to delete the term "butchering" and clarification of the methods step being carried out.

Claim 78 rejected under 35 U.S.C. 112, second paragraph, in light of the amendment of claim 77 to provide antecedent basis for the phrases recited in claim 78.

Claim 79 rejected under 35 U.S.C. 112, second paragraph, in light of the amendment of of claim 79 to depend from claim 76, which has been amended to be directed to a method of producing a safer food source and to provide antecedent basis for the phrases recited in claim 79.

Claim 82 rejected under 35 U.S.C. 112, second paragraph, in light of the amendment of the claim to no longer recite the term "butchering".

Claims 60, 66, 71, 76, 87 (being read to include oral ingestion of food or water containing intimin for generating anti-intimin antibodies) rejected under 35 U.S.C. 102(b) as being anticipated by Cravioto et al (1991) , in light of the claims having been amended to recite the step of "administering" instead of "generating" antibodies.

7. Claim 60,66-70, 76,77, 83, 85-86, 89,90 rejected under 35 U.S.C. 103(a) as being unpatentable over Dougan et al (US Pat. 5,747,293), in light of the amendment of the claims to recite the methods steps of "administering" and the phrase "from the host to the patient".

Rejections Maintained

8. Amended and Newly submitted claims 60, 66-71, 76-77, 80-81, 83, 85-88, 73-75, 84, 91-94, 78-79 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Childlow et al (US Pat. 4,141,970) in view of Cravioto et al (1991), as previously applied to claims 60, 66-71, 76-77, 80-81, 83, 85-88 .

9. Amended and Newly submitted claims 60, 66-71, 76-77, 80-81, 83, 85-90, 73-75, 84, 91-95, 78-79, 82 and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dougan in view of Childlow et al (US Pat. 4,141,970).

Response to Arguments

10. The rejection of claims 60, 66-71, 76-77, 80-81, 83, 85-88, 73-75, 84, 91-94, 78-79 and 82 under 35 U.S.C. 103(a) as being unpatentable over Childlow et al (US Pat. 4,141,970) in view of Cravioto et al (1991)as previously applied to claims 60, 66-71, 74, 76-77, 80-81, 83-88 was not specifically traversed but Cravioto et al alone was argued.

11. It is the position of the examiner that the rejection made of record was Childlow et al in view of Cravioto et al, this rejection was not addressed. Applicant's arguments did not address the rejection made of record. The rejection of the claims under 35 U.S.C. 102(b) over Cravioto et al alone was previously withdrawn in paper number 31, dated August 15, 2001.

Childlow et al is directed to a method of providing a safer food supply, wherein the method of passively immunizing a patient is through active immunization, the administration of a composition that comprises E.coli 0157 (includes intimin) to of a milk producing mammal and administering the generated antibodies to an offspring, during a modern stock-raising practice (see col. 1, lines 30-33).

Childlow et al teach that the sows, cows and ewes are to have the antigen composition administered to thereto, prior to or after breading (see col. 2, lines 16-23). Stock-raising practice

includes, raising (stock raising, col. 1, line 32), breeding (pregnant mother animals, (see col. 2, line 6), and preparing (stock raising practice, improved health and weight gain (see col. 1, line 16 and 26) for food (modern stock-raising). Among the animals immunized are food source animals, specifically pigs, cows and sheep (see col. 2, line 29).

The rejection of the claims under 35 U.S.C. 103(a) Childlow et al in view of Cravioto et al is maintained for reasons of record.

12. The rejection of claims 60, 66-71, 76-77, 80-81, 83, 85-90, 73-75, 84, 91-95, 78-79, 82 and 96 under 35 U.S.C. 103(a) as being unpatentable over Dougan in view of Childlow et al (US Pat. 4,141,970), as previously applied to claims 60, 66-71,74, 76-77, 80-81, 83-90, is traversed through arguing the Dougan et al reference.

13. It is the position of the examiner that the rejection made of record was Dougan in view of Childlow et al, this rejection was not addressed; Applicant's arguments did not address the rejection made of record. The rejection of the claims under over Dougan et al alone was previously withdrawn in paper number 31, dated August 15, 2001. The rejection of the claims under 35 U.S.C. 103(a) Dougan in view of Childlow et al is maintained for reasons of record.

The discussion of Childlow et al above, and the application of the combination of Dougan in view of Childlow references to the newly amended or new claim is for the reasons set forth above under paragraph 11. The combination of references obviate the instantly claimed invention.

14. Applicant asserts that Exhibit A, a reference entitled "The immunoglobulins and immunoglobulin genes of swine" Vet. Immunol. Immunopathology 1994, together with evidence previously submitted to data presented in the Dean-Nystraom abstract" set forth a showing of unexpected results thus obviating the prima facie case of obviousness.

15. It is the position of the examiner that the prior art applied to the claims, specifically showed passive immune transfer from a mother to a child for providing a protective immune response to the child directed against E.coli O157.

Protection through administration of enriched composition that comprises intimin of E.coli 0157 antigen was carried out and claimed by Childlow et al. Evidence showing protection against infection with an enriched composition has been described in the prior art. Protection would be expected, and a showing of protection does not show unexpected results.

With respect to the previous submission of the Dean-Nystrom Abstract. It is the position of the examiner that the antibodies administered to the piglets were obtained through an immunization process where the host was vaccinated twice (see abstract, line 10). The antibodies were administered in colostrum, with titers of greater than or equal to 100,000. The claimed invention does not recite the limitations of first and second vaccinating steps, the antibodies are not limited only to colostral antibodies, and no claims require any specific titer or concentration. With respect to administering the amount of generated anti-intimin antibodies directly from the pregnant animal to its offspring, the type of antibodies are not defined to be colostral antibodies and could be placental immunoglobulins passed directly from the pregnant animal to the offspring.

The amount of generated antibodies administered is not defined by titer, by length time of suckling nor limited to a pregnant pig. The results shown in the abstract that are commensurate in scope with the claimed invention.

This position is based upon the definition of "enriched" provided in Applicant's specification at page 7, first paragraph : [to an enriched protein comprising intimin] ...[that induces antibodies that block wild-type binding activity]. Clearly the definition provides for the administration of an enriched intimin composition that is present in an inactivated whole cell, or whole cell lysate composition, that will induce an immune response to intimin. Childlow et al clearly teaches this composition (E.coli O157 (col. 3, line 11) and, col. 2, lines 66-67 and col. 3, lines 1-7), and Dougan et al teach a conserved, receptor associated portion of intimin for administration and induction of an immune response that will block binding and treat infection (see Dougan et al, '293, col. 2, lines 43-44).

The claimed invention is obviated for reasons of record.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

17. Oaks et al (US Pat. 6,277,379 and 6,245,892) is cited to show a method of generating antibodies for prophylactic or therapeutic purposes through administering an intimin like protein to a host (see '379: claim 9, col.26, lines 21-27 and '892 all claims).

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242. The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
September 26, 2002

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